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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,644	01/20/2004	Christopher B. Newgard	5405-301	1840

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EXAMINER
CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
1652	

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DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,644	NEWGARD ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 7-8, and 13-16, drawn to a method of enhancing fuel-stimulated insulin secretion in a subject, comprising administering to the subject a compound that modulates lactate dehydrogenase (LDH) activity in an amount effective to modulate LDH activity, thereby enhancing fuel-stimulated insulin secretion, wherein the compound is antibody, classified in class 435, subclass 189.

II. Claims 1-6, 9-10, 13-16, and 43-50, drawn to a method of enhancing fuel-stimulated insulin secretion in a subject, comprising administering to the subject a compound that modulates lactate dehydrogenase (LDH) activity in an amount effective to modulate LDH activity, thereby enhancing fuel-stimulated insulin secretion, wherein the compound is a DNA molecule, classified in class 435, subclass 69.1.

III. Claims 1-6, 9, 11, and 13-16, drawn to a method of enhancing fuel-stimulated insulin secretion in a subject, comprising administering to the subject a compound that modulates lactate dehydrogenase (LDH) activity in an amount effective to modulate LDH activity, thereby enhancing fuel-stimulated insulin secretion, wherein the compound is a RNA molecule, classified in class 435, subclass 69.1.

IV. Claims 1, 17 and 23-28, drawn to a method of identifying a compound, which modulates LDH activity by contacting the LDH polypeptide, classified in class 435, subclass 15.

V. Claim 1, 18-21, and 29-37, a method of identifying a test compound which modulates LDH activity in a cell system, classified in class 435, subclass 7.21.

VI. Claim 1, 22 and 42, drawn to a method for identifying a compound by administering the compound in a transgenic non-human mammal, classified in class 435, subclass 15.

VII. Claim 38-41, drawn to a transgenic non-human mammal comprising an isolated nucleic acid encoding LDH, which is stably integrated in pancreatic beta cells of said transgenic animal, classified in class 800, subclass 13.

VIII. Claims 51-52, drawn to a method of treating non-insulin dependent diabetes mellitus by administering to a human subject a nucleic acid encoding LDH, classified in class 514, subclass 789.

IX. Claims 53-58, and 64-67, drawn to an isolated nucleic acid molecule encoding a mitochondrial lactate dehydrogenase-A (LDH_A), classified in class 536, subclass 23.2.

X. Claims 59-63, drawn to a polypeptide of a mitochondrial lactate dehydrogenase-A (LDH_A), classified in class 435, subclass 189.

For each of inventions I-X above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions I-X and one of inventions (A) – (D).

(A). protein of SEQ ID No: 2 or a nucleic acid encoding SEQ ID No: 2.

(B). protein of SEQ ID No: 4 or a nucleic acid encoding SEQ ID No: 4.

(C). protein of SEQ ID No: 25 or a nucleic acid encoding SEQ ID No: 25.

(D). protein of SEQ ID No: 27 or a nucleic acid encoding SEQ ID No: 27.

The inventions are distinct, each from the other because of the following reasons:

2. The DNA of Group IX and the protein of Group X and transgenic animal of Group VII, each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA of Group IX comprises a nucleic acid sequence and the protein of Group X comprises amino acid sequence. The DNA has other utility besides encoding the proteins such hybridization or probe preparation and the protein can be made by another method such as isolation from natural sources or chemical synthesis. Transgenic animal can be made by using materially different nucleic acids molecules.

3. Inventions IX, and VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used for hybridization or probe preparation.

4. Inventions IX, and II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used for hybridization or probe preparation.

5. Inventions X and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used for inducing antibody.

6. Inventions IX, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used for hybridization or probe preparation.

7. Inventions polynucleotide Group IX is unrelated to the methods of Groups I, III, IV, and VI as nucleic acid of Group IX is neither used nor made by the methods of Groups I, III, IV, and VI and they have different modes of operation and different functions.

8. Inventions polypeptide Group X is unrelated to the methods of Groups I, II, V, and VI-VIII as polypeptide of Group X is neither used nor made by the methods of Groups I, II, V, and VI-VIII and they have different modes of operation and different functions.

9. The methods of groups I-VIII are patentably distinct as they comprise unrelated steps, as using different products and produce different effects.

10. The nucleic acid and proteins of Group (A)-(D) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polypeptides and polynucleotide encoding them. Therefore, where structural identity is required, such as for hybridization or expression or antibody binding, the different sequences have different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48b if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the imitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal H. Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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